tal effects of such therapy. A normal androgen milieu is important for prostatic growth and the production of PSA. It stands to reason, therefore, that hypogonadal men might present with decreased serum PSA levels and that androgen replacement would increase PSA values in comparison to those seen in eugonadal men. Whether such replacement therapy might increase the risk of detectable prostate cancer remains a topic of discussion. The report reviewed here, however, suggests that, in the short term, this does not appear to be the case. ■

Dr Meacham serves on the Speakers' Bureau and Advisory Boards of Solvay Pharmaceuticals and Auxilium Pharmaceuticals.

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Erectile Dysfunction

A New Quality-of-Life Scoring Instrument for Patients With Erectile Dysfunction

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Measuring subjective outcomes has become an important part of both urologic practice and research. Indices are now available to aid in the evaluation and management of many urologic conditions, including benign prostatic hyperplasia, prostate cancer, incontinence, and sexual dysfunction. Investigators have utilized the newly emerging fields of clinimetrics and psychometrics to validate and standardize these instruments, making them reliable and reproducible. The resultant tools help clinicians evaluate the impact of both disease and treatments. Most of these indices focus on specific diseases and attempt to evaluate the impact of the condition on patient quality of life.

Psychological Impact of Erectile Dysfunction: Validation of a New Health Related Quality of Life Measure for Patients with Erectile Dysfunction

Latini DM, Penson DF, Colwell HH, et al.

J Urol. 2002;168:2086-2091.

Latini and colleagues have developed an addition to this armamentarium of indices in an attempt to evaluate the psychological impact of erectile dysfunction (ED), a condition generally perceived as having a significant effect on patient quality of life. Although this is not the first self-administered questionnaire to attempt to measure the psychological impact of ED, it is distinguished from others in its ability to calculate separate subscales for sexual performance and overall impact of ED on emotional well-being. The 16-item index (Table 1) has a slightly complicated scoring system but a comprehensive (if somewhat dramatically worded) list of questions, covering the range of emotions experienced by men with ED. It is a welcome addition in the arena of sexual dysfunction diagnosis and treatment. Future studies testing its consistency and overall usefulness should prove interesting. ■

Prostate Cancer

Expectant Management of Prostate Cancer

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The widespread use of prostate-specific antigen (PSA) testing for the detection of prostate cancer over the past 2 decades has led to earlier diagnosis and treatment of the condition.[1] To this end, Carter and colleagues[1] studied 240 men who underwent radical retropubic prostatectomy (RRP), between 1994 and 1996, for stage T1c cancers and compared the results to those of an earlier, similar study conduced by Epstein and associates.[2] Carter and colleagues found an increase in organ-confined disease and a decrease in positive margin status compared with the earlier study (72% vs 51% and 8% vs 17%, respectively).[1] However, using the pretreatment "significance" criteria described by Epstein and associates,[2] which is based on PSA

Table 1
Psychological Impact of Erectile Dysfunction, Version 1.0

Over the past 4 weeks . . .
(Please check the response that fits best by marking the box)

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
1. I am more irritable than I used to be.	❑	❑	❑	❑	❑
2. At times, I have felt so devastated by the performance of my penis that I wanted to die.	❑	❑	❑	❑	❑
3. My erectile dysfunction makes me feel like less of a man.	❑	❑	❑	❑	❑
4. I lack masculine confidence.	❑	❑	❑	❑	❑
5. I am easily frustrated by little things.	❑	❑	❑	❑	❑
6. When I have trouble with my erection, I feel disgusted by my penis.	❑	❑	❑	❑	❑
7. I feel proud of my penis.	❑	❑	❑	❑	❑
8. My erectile dysfunction makes me feel sexually unattractive.	❑	❑	❑	❑	❑
9. When I can't have intercourse, I don't feel like having any sex at all.	❑	❑	❑	❑	❑
10. Sex feels like it is not worth the effort.	❑	❑	❑	❑	❑
11. I feel there's something missing in my sex life when I can't have intercourse.	❑	❑	❑	❑	❑
12. I avoid sexual opportunities.	❑	❑	❑	❑	❑
13. I don't quite believe my partner(s) when they say they are satisfied with my sexual performance.	❑	❑	❑	❑	❑
14. I am afraid to touch my partner in ways that will make her want to have sex with me.	❑	❑	❑	❑	❑
15. I feel I could not sustain a new relationship because of my erectile dysfunction.	❑	❑	❑	❑	❑
16. My frustration over my erectile dysfunction has a negative effect on my sexual relationship(s).	❑	❑	❑	❑	❑

Scoring instructions:
Scale 1) Psychological impact of erectile dysfunction on sexual experience. Score only if at least 8 of the 11 items have been completed. Impute a value for missing items by assigning the mean value of the nonmissing items. Calculate the sum of items 3, 4, 6, 8, 9, 10, 11, 12, 14, 15, and 16. Transform the summed score into a T score (mean ± SD 50 ± 10). Higher scores indicate greater psychological impact.

Scale 2) Psychological impact of erectile dysfunction on emotional life. Reverse code item 7. Score only if at least 4 of the 5 items have been completed. Impute a value for missing items by assigning the mean value of the nonmissing items. Calculate the sum of items 1, 2, 4, 7, and 13. Transform the summed score into a T score (mean 50 ± 10). Higher scores indicate greater psychological impact.

PIED, Psychological Impact of Erectile Dysfunction, ©1999-2002 TAP Pharmaceutical Products Inc.
Reprinted with permission from Latini DM et al. *J Urol*. 2002;168:2086-2091.

density (<0.15 ng/mL per cm^3) and pathologic findings (Gleason score ≤6, <3 cores containing cancer, and <50% cancer involvement of any core), Carter and colleagues determined that the percentage of insignificant cases for which RRP was performed remained stable (16% vs 17%), despite an increase in the detection of stage T1c disease since the availability of serum PSA testing.[1]

Approximately 20% to 30% of men undergoing PSA testing in referral and screened populations will have prostate cancer that is well to moderately differentiated (Gleason score ≤6) and less than 0.5 cm^3 in volume.[2,3] Furthermore, small-volume, lower-grade cancers are thought to be less clinically significant and demonstrate a long natural history.[2] Thus, older men with well to moderately differentiated cancers that are small in volume may not benefit from treatment of disease that is not destined to cause harm during their lifetime.

In order to avoid unnecessarily treating potentially insignificant prostate cancer, the concept of expectant management, also known as watchful waiting or deferred therapy, has gained popularity over the past 4 to 5 years. Expectant management is most often thought of as an alternative to active treatment; if progression of disease becomes apparent at follow-up, active treatment is then initiated. With this in mind, Carter and colleagues[4] recently published preliminary results of a study in which 81 men with stage T1c prostate cancer were followed with expectant management. Twenty-five subjects (31%) had disease progression at follow-up. Of these 25 men, 13 underwent RRP and 12 (92%) had curable disease. Hence, the authors concluded that expectant management with curative intent might be a reasonable alternative for carefully selected older men who are thought to have small-volume, insignificant cancers.

Although expectant management has generated a great deal of interest, until recently there has been a lack of comparison between active and expectant management in relation to long-term survival outcomes. The following 2 studies address this issue in a retrospective analysis and a prospective study. The final article reports on quality of life in patients treated by RRP or expectant management for localized prostate cancer.

Outcomes for Men With Clinically Nonmetastatic Prostate Carcinoma Managed With Radical Prostatectomy, External Beam Radiotherapy, or Expectant Management: A Retrospective Analysis

Barry MJ, Albertsen PC, Bagshaw MA, et al.
Cancer. 2001;91:2302-2314.

The authors conducted a retrospective cohort study, which included all Connecticut hospitals (expectant management cohort) and 3 academic medical centers in other states (radiotherapy and surgery cohorts). In total, 2311 consecutive men, aged 55 to 74 years, who were diagnosed with nonmetastatic prostate cancer from 1971 to 1984 and managed with the appropriate strategy for that center were included in the study. Kaplan-Meier estimates with 95% confidence intervals (CI) of overall survival at 10 years for each cohort were as follow: expectant management, 42% (95% CI, 38%-46%); radiotherapy, 52% (95% CI, 46%-58%); and RRP, 69% (95% CI, 67%-71%). Disease-specific mortality estimates were as follow: expectant management, 75% (95% CI, 71%-79%); radiotherapy, 67% (95% CI, 61%-73%); and RRP, 86% (95% CI, 84%-88%).

The results of this study provide estimates of outcomes for patients with nonmetastatic prostate carcinoma treated with different modalities. However, as the cohorts differed substantially in terms of measured prognostic factors (eg, Gleason score, digital rectal examination findings, and age at diagnosis), the authors appropriately concluded that direct comparisons of outcomes among treatment groups are inadvisable because of the different demographics of men who select these alternative management strategies. It should also be noted that many of the patients included in the study were diagnosed prior to the PSA era. Hence, outcomes may have been different if only patients diagnosed after the widespread introduction of PSA testing were included in the study.

A Randomized Trial Comparing Radical Prostatectomy With Watchful Waiting in Early Prostate Cancer

Holmberg L, Bill-Axelson A, Helgesen F, et al, for the Scandinavian Prostatic Cancer Group Study Number 4.
N Engl J Med. 2002;347:781-789.

These authors report on the results of a landmark study that investigated whether RRP has any survival benefit over expectant management in patients with early (organ-confined) prostate cancer. Between 1989 and 1999, 695 men with newly diagnosed prostate cancer (clinical stage T1b, T1c, or T2) were randomly assigned to either expectant management or RRP. The primary end point of the study was death resulting from prostate cancer; secondary end points were overall mortality, metastasis-free survival, and local progression. During the median follow-up period of 6.2 years, 31 (8.9%) of 348 patients in the expectant management group and 16 (4.6%) of 347 patients in the RRP group died from prostate cancer (relative hazard, 0.50;

95% CI, 0.27-0.91; $P = .02$). In addition, there was a 14% absolute reduction in the rate of development of distant metastases in the RRP group compared with the expectant management group (relative hazard, 0.63; 95% CI, 0.41-0.96). However, overall deaths in the expectant management and RRP groups were not significantly different (62 of 348 patients and 53 of 347 patients, respectively; $P = .31$).

The median survival time for men with metastatic prostate cancer is only 2 to 3 years.[5] Therefore, it will be interesting to see whether differences between the 2 groups in the overall mortality rates become apparent over the next few years. It is also important to note that 75% of the patients in this study had palpable disease and only 10% of cases were detected because of an elevated serum PSA level. These patients, therefore, do not reflect most patients seen today in the United States, where 75% of patients diagnosed with prostate cancer have nonpalpable disease.[6] Therefore, the lead time in diagnosis (≥5 years) must be taken into account before the findings of this study can be applied to contemporary patients.[7]

Expectant management is still appropriate for elderly patients and patients who have significant comorbidities such that life expectancy is less than 10 years.

In conclusion, expectant management is still appropriate for elderly patients and patients who have significant comorbidities such that life expectancy is less than 10 years. If these patients become symptomatic, palliative treatment can be instigated. Furthermore, 10% to 20% of men with nonpalpable disease have small-volume tumors and may also be candidates for expectant management. However, younger healthy men with significant localized prostate cancer should be considered for definitive treatment.

Quality of Life After Radical Prostatectomy or Watchful Waiting

Steineck G, Helgesen F, Adolfsson J, et al, for the Scandinavian Prostatic Cancer Group Study Number 4.
N Engl J Med. 2002;347:790-796.

The authors evaluated symptoms and self-assessments of quality of life in the group of men with localized prostate cancer who had participated in the randomized comparison study of RRP and expectant management conducted by Holmberg and colleagues and reviewed above. Data were collected at least 12 months after surgery and 14 months after randomization. Men younger than 75 years with a life expectancy of more than 10 years were eligible for inclusion in the study. Of the 376 eligible men, 326 (87%) agreed to participate. The results demonstrated that erectile dysfunction (ED) and urinary incontinence were more common after RRP compared with expectant management (80% vs 45% and 49% vs 21%, respectively), whereas urinary obstruction was less common (28% vs 44%, respectively). Bowel function, prevalence of anxiety and depression, well-being, and subjective quality of life were similar in the 2 groups. Therefore, the authors concluded that expectant management and RRP entail different risks of ED, urinary incontinence, and urinary obstruction, but have little influence on well-being or subjective quality of life.

Nerve-sparing surgery was not routinely performed in this study. In addition, many subjects were older than 65 years, and 28% received hormonal therapy during follow-up. Furthermore, 75% of subjects had palpable disease, which is significantly higher than the rate in US patients seen today.[6] Hence, these factors may account for the high prevalence of ED and urinary incontinence compared with contemporary US patients undergoing radical prostatectomy.[8] Nevertheless, it is interesting to note that, although it resulted in a higher prevalence of ED and urinary incontinence, RRP did not adversely affect patients' well-being or subjective quality of life compared with expectant management. This may, in part, be related to the higher prevalence of urinary obstructive symptoms experienced by patients who are managed expectantly. ■

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